## REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks. Claims 8-83 have been withdrawn. Claims 1-83 are pending.

### *Claim Rejections – 35 USC 102*

Claims 1-5 are rejected under 35 USC 102(b) as being anticipated by Rabbani et al. (EP 0971039). Applicants respectfully traverse the rejection.

Claim 1 recites a second primer that includes a folded sequence (D-Dc') that contains, on the same strand, two nucleic acid sequences that hybridize to each other.

Advantageously, when the first and second primers according to claim 1 are used, a target gene can be amplified efficiently under isothermal conditions with high specificity. The advantageous effects of claim 1 are demonstrated, for example, by Example 4 on pages 63-66 of the present specification.

In particular, Example 4 involves the use of a specific region of a human STS DYS237 gene or the specific region of the human STS DYS237 gene having a single nucleotide mutation as a template for amplification of the regions under isothermal conditions (pages 63-64 of the specification). Primers in accordance with claim 1 were prepared, where the only difference between the primers for detecting the non-mutated region (R1 and F1, which correspond to the first and second primers of claim 1, respectively) and the primers for detecting the mutated region (R1G and F1, which correspond to the first and second primers of claim 1, respectively) is a single nucleotide in the sequence (B') of the first primer (the difference is at the fifth residue from the 5' end of R1 and R1G; see page 63 and Figure 8 of the specification). The sequence (B') as recited in claim 1, is a sequence on the primer that hybridizes to the complementary sequence (Bc) of the sequence (B) on the target nucleotide sequence. The single nucleotide change in R1G corresponds to the single nucleotide mutation in the specific region of the human STS DYS237 gene. As shown in Fig. 9, F1 and R1 amplified the non-mutated region but not the mutated region, while F1 and R1G amplified the mutated region but not the non-mutated region. The amplified products were achieved in as little as one hour. These results indicate that the primers in accordance with claim 1 allow highly specific amplification to be achieved such that even a single nucleotide mutation

can be detected in a gene, and the highly specific amplification can be conducted efficiently.

Rabbani does not disclose a second primer that includes a folded sequence (D-Dc') that contains, on the same strand, two nucleic acid sequences that hybridize to each other. That is, Figure 1 of Rabbani describes the steps involved in a linear amplification using a primer having first (C) and second (B') segments (see page 9 of Rabbani). The first segment B' includes a sequence that is complementary to a sequence in segment B of the target gene (*Id.*). The second segment C includes a sequence that is identical to a sequence in segment C of the target gene (*Id.*). Rabbani explains that in step 1, the second segment B' of their primer binds to segment B of the target gene (*Id.*). In step 2, the template dependent extension of their primer produces an extended portion sequence that contains a segment (C') that includes a sequence that is complementary to the sequence in the first segment (C) of their primer (*Id.*). Rabbani indicates that the resulting elongated strand contains self-complementary regions such that a secondary structure, and in particular, a loop, can be formed, as shown in step 3 of Figure 1 (*Id.*). Thus, Rabbani discloses that an elongated strand that is formed by a template dependent extension of a primer, as opposed to the primer itself, has a self-complementary region.

On the other hand, claim 1 recites a second primer that contains a folded sequence (D-Dc') that contains, on the same strand, two nucleic acid sequences that hybridize to each other. Advantageously, when the first and second primers according to claim 1 are used, a target gene can be amplified efficiently under isothermal conditions with high specificity, as demonstrated, for example, in the experimental work of the present specification. Nothing in Rabbani teaches or suggests the features of claim 1, or its benefits. Accordingly, claim 1 and its dependent claims are patentable over Rabbani.

Claims 5-7 are rejected under 35 USC 103(a) as being unpatentable over Rabbani as applied to claims 1-5 above, in view of Pastinen et al. (Genome Research, 1997, vol. 7, pp. 606-614). Applicants respectfully traverse the rejection.

Claim 1 has been distinguished above from Rabbani. Pastinen does not remedy the deficiencies of Rabbani. Claims 5-7 depend from claim 1, and are patentable over

Rabbani and Pastinen for at least the same reasons discussed above. Applicants do not concede the correctness of the rejection.

In view of the foregoing, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,



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